

REMARKS

Claims 1 and 19 have been amended and claims 21-32 have been added. Claims 21-32 contain no new matter. Claims 1-19 and 21-22 are pending. Claims 1-19 have been rejected.

I. Introduction.

In the Office Action mailed February 8, 2006, the Examiner rejected the claims on the following grounds: 1) Claims 1-18 were rejected under 35 U.S.C. §112 as indefinite in light of the use of certain terms in the claims; 2) Claims 1-3, 6, 7, and 13-18 were rejected under 35 U.S.C. §102(b) as anticipated by U.S. Pat. No. 5,562,642; 3) Claims 4, 5, and 8-12 were rejected under 35 U.S.C. §103 as obvious in light of U.S. Pat. No. 5,562,642; and 4) Claim 19 was rejected under 35 U.S.C. §103 as obvious in light of U.S. Pat. Nos. 6,183,766; 5,562,642; 6,861,397; and 5,821,237. Applicant respectfully traverses these rejections and requests reconsideration for the reasons stated below.

II. The Rejections under 35 U.S.C. §112.

It is the Examiner's position that because the claims use the terms "substantially uniformly absorb," "substantially retained," and "substantially uniformly delivered," they do not particularly point out and distinctly claim the subject matter which the applicant regards as the invention. It is the Applicant's position that one skilled in this art would readily appreciate the meaning of these terms as used in the pending claims and that the claims therefore satisfy the requirements of 35 U.S.C. §112.

As a preliminary matter, the Applicant notes that the terms "absorb," "retained," and "delivered" have the meanings ordinarily given to them in this art. Applicant does not believe that it can be seriously maintained that one skilled in this art does not readily understand the meanings of these terms. If the Examiner is of the opinion that these terms would not be clearly understood by one skilled in this art, the Applicant requests that the basis for this opinion be clearly stated so that the Applicant may respond to it.

As to the modifiers "substantially" and "substantially uniformly," it is the Applicant's position that these do not render the well-understood terms "absorb," "retained," and "delivered"

indefinite or unclear. The Federal Circuit has explicitly endorsed the use of these modifiers in claim language.

According to the Federal Circuit, the use of the term "substantially" is proper and definite when used in claim language. In discussing the term "substantially equal," the court states that "[s]uch usages, when serving to reasonably to describe the claimed subject matter to those of skill in the field of the invention, and to distinguish the claimed subject matter from the prior art, have been accepted in patent examination and upheld by the courts." *Andrew Corp. v. Gabriel Electronics, Inc.*, 847 F.2d 819, 821 (Fed. Cir. 1988); see also MPEP §2173.05(b). Further, "without an express intent to impart a novel meaning to claim terms, an inventor's claim terms take on their ordinary meaning." *York Products, Inc. v. Central Tractor Farm & Family*, 99 F.3d 1568, 1572 (Fed. Cir. 1996). In the instant specification, as in *York*, the application discloses no novel uses of the words. Thus, "'substantially' means considerable in ... extent,' *American Heritage Dictionary Second College Edition* 1213 (2d ed. 1982) or 'largely but not wholly that which is specified,' *Webster's Ninth New Collegiate Dictionary* 1176 (9th ed. 1983)." *York*, 99 F.3d at 1572-73. In *Ecolab, Inc. v. Envirochem, Inc.*, the court stated that "[o]rdinarily, 'uniform' means 'always the same as in form or degree; unvarying.' *The American Heritage Collection Dictionary* 1475 (3d ed. 1997)." *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1366 (Fed. Cir. 2001). The court in *Ecolab*, found that the "language 'substantially uniform'" expressly modifies the term 'alkaline detergent'" and is acceptable claim drafting practice. *Ecolab*, 264 F.3d at 1366. Similarly, in the pending claims the language "substantially uniform" modifies the terms "absorb" and "delivered" and therefore, is proper claim language. Further, the terms "retained" and "delivered" have their ordinary meaning and are described as such in the instant specification. See Specification, p. 3, paragraph 11 and p. 4, paragraph 14.

For example, the term "uniformly absorb" is discussed in the specification and specifically at page 8, paragraph 33, which states, "the composition may be an emulsion which is substantially uniformly absorbed via capillary action to the pad, and the composition remains on the pad in the container and a therapeutic amount of medication in the composition is discharged to the skin upon wiping the pad across the skin." Page 8, paragraph 33. Additionally, dermatologically active ingredients "do not preferentially migrate or adsorb from the composition . . . onto or into the pad, and therefore does not result in an uneven concentration of

the dermatologically active ingredient in the composition versus the pad.” Page 3, paragraph 11. The specification also discusses the tests performed and shows photos to show the substantially uniform application of the composition from the pad to the skin. *See Tests 2 and 3.* To achieve such uniformity, one of ordinary skill in the art would understand the meaning of the term “substantially uniformly absorb” and the scope of the claims as a whole.

The term “retained” is discussed throughout the specification and specifically at page 3, paragraph 11, which states, “[t]he composition is retained by the pad preferentially over the container.” The specification also discusses tests performed to determine whether the BPO in the composition was excessively transferred from the pad to the inside of the container. Page 9, paragraph 37 – page 10, paragraph 38, and Test 1. Given the disclosure provided in the specification, one of ordinary skill in the art would understand the meaning of the term and the scope of the claims as a whole.

The term “uniformly delivered” is discussed throughout the specification and specifically at page 4, paragraph 14, which states, “[u]se of the present invention by wiping the pad across the skin results in a transfer to the skin of the dermatologically active ingredient, meaning that the skin is substantially uniformly medicated.” Further, the specification includes photos of skin with BPO delivered from the invention and discusses tests performed to determine whether the composition applies substantially uniformly to the skin via the pad. *See page 10, paragraphs 39-44, and Tests 2 and 3.* Based upon the disclosure in the specification, including the experiments performed to illustrate the substantially uniform delivery of a composition, one of ordinary skill in the art would understand the meaning of the term and the scope of the claims as a whole.

As evident from the instant specification the terms “retain,” “absorb,” and “delivered” all have the ordinary meaning of the terms. The ordinary meaning of the term “retained” is “to hold secure or intact.” <http://www.m-w.com/dictionary/retained> (April 24, 2006); *See Exhibit 1.* The ordinary meaning of the term “absorb” is “to suck up or take up.” <http://www.m-w.com/dictionary/absorb> (April 24, 2006); *See Exhibit 2.* The ordinary meaning of the term “delivered” is “to send (something aimed or guided) to an intended target or destination.” <http://www.m-w.com/dictionary/delivered> (April 24, 2006); *See Exhibit 3.* It is also important to point out that according to the MPEP § 2173.02, “[an examiner] should allow claims which

define the patentable subject matter with a reasonable degree of particularity and distinctiveness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire." Therefore, the term "substantially" (permitted by the Federal Circuit) used in the instant claims modifies the term "retained" and the term "substantially uniformly" (permitted by the Federal Circuit) modifies the terms "absorb," and "delivered," which are all set forth in the instant specifications and satisfy the 35 U.S.C. §112, 2nd paragraph requirement.

Thus, the Applicant's use of the terms "substantially uniformly absorb," substantially retained," and "substantially uniformly delivered" is consistent with the statute, with the decisions of the Federal Circuit, and with Office policy as set forth in the MPEP. The rejections under §112 should be withdrawn.

III. Rejections Under §102.

Claims 1-3, 6, 7, and 13-18 were rejected under 35 U.S.C. §102(b) as anticipated by U.S. Pat. No. 5,562,642 (the '642 Patent).

Before addressing the disclosures of the '642 Patent, a few words concerning the instant invention are in order. Among other things, this invention deals with several problems faced in the art.

One of these problems relates to the topical delivery of insoluble, particulate therapeutic agents by way of a cloth or pad. As was pointed out in the application at paragraph 10, pads have been used to topically deliver therapeutic liquids or solutions such as, Stri-Dex Pads, which are a pad delivery system for a salicylic acid solution. However, particulate therapeutic agents have posed serious problems for cloth or pad delivery systems. For example, the pads often act to filter out the particles from the liquid and retain the particles on the pad matrix. For insoluble, particulate therapeutic agents, such as benzoyl peroxide, this can result in the retention of so much of the therapeutic agent on the pad or cloth that a sub-optimal or even sub-therapeutic amount of the agent is delivered to the skin.

Another problem confronted by this invention has to do with the difficulty in controlling the "release" of the fluid from the pad. One must firmly retain the particle-containing fluid on

the cloth or pad applicator prior to use, but readily release the particle-containing fluid from the applicator pad or cloth when actually used. A related problem arises when the cloth or pad applicator is stored in a pouch or similar container. The fluid must be retained on the pad and not released to the inside walls of the pouch, since this would leave the fluid in the container, unavailable for its intended use (e.g. application to the skin). One of the problems of the prior art is illustrated by the high viscosity taught in U.S. 5,821,237 ('237 Patent)¹. Using a composition with the suggested viscosities of the '237 Patent on a pad would result in the problems associated with insoluble ingredients and pads, which is solved by the present invention.

As is pointed out in the specification at paragraph 13, these problems are solved by controlling the viscosity of the fluid that is to be applied by the pad. Viscosity must be low enough to allow the fluid to penetrate the pad and to adhere to the pad in preference to the walls of the container, yet viscosity must be high enough to prevent the liquid from draining off the pad (which can sometimes leave the insoluble particles behind on the pad). It has also been found that keeping the particle size of the insoluble material below a certain size also assists in solving these problems, especially the problem of the pad filtering out the particulates from the composition before it is deposited on the skin. These features are specifically recited in the pending claims.

Applicant turns now to the rejection under 35 U.S.C. §102(b) in light of the '642 Patent. The Examiner concedes that the '642 Patent does not disclose controlling either viscosity or particle size, and states that claims that recite these limitations are not subject to this rejection. See, the paragraph bridging pages 4 and 5 of the Office Action. Unfortunately the Examiner has overlooked the viscosity limitation that originally appeared at line 6 of Claim 1, and has been amplified by the current claim amendments. By the Examiner's own reasoning, the presence of this limitation in Claim 1, and in Claims 2-3, 6, 7, and 13-18 which depend from it, rules out a rejection of these claims under 35 U.S.C. §102(b) in light of the '642 Patent. Withdrawal of this rejection is therefore requested.

¹ The '237 Patent was cited by the Examiner under the 35 U.S.C. §103 rejection of claim 19.

IV. Rejections under 35 U.S.C. §103.

The Examiner has advanced two rejections under 35 U.S.C. §103. The Applicant believes that neither rejection can be properly maintained.

a) Rejection of Claims 4, 5, & 8-12.

The Examiner has rejected claims 4, 5, and 8-12 under 35 U.S.C. §103 on the basis of a single reference: the '642 Patent. In advancing this rejection, the Examiner again concedes that the '642 patent does not teach the particle size and viscosity limitations of these claims. Indeed, the '642 Patent makes no mention of the viscosity of the liquid that is applied to the pad or cloth. Similarly, there is no mention in the '642 Patent of the size of the insoluble particles that are used. The Examiner has taken the position that it would simply be expected that these limitations would be met by the prior art. The Examiner's argument is simply a hindsight attribution of the invention to the prior art, and cannot properly form the basis for the rejection of these claims.

At page 6 of the Office Action the Examiner states that "the composition disclosed by US '642 ... comprises the same elements disclosed by applicants that are retained in [the] pad of non-woven material inside [a] container made of metal and plastic." This statement is true only in that the reference discloses a liquid that has insoluble particles on a pad in a container. The '642 Patent does not mention viscosity or particle size at all, much less the specific ranges called for by claims 4, 5, and 8-12. Thus, it cannot be fairly said that the '642 Patent discloses a composition that has "the same elements disclosed by applicants." Indeed, if the '642 Patent disclosed compositions having the same elements disclosed by applicants, the '642 Patent would properly be the basis for a rejection under 35 U.S.C. §102 – which the Examiner concedes is not the case.

The Examiner supplies the missing viscosity claim element by asserting that "it is expected" that the viscosity would be the same. This assertion is flatly contradicted by the art of record. The '642 Patent does not mention the viscosity of the liquid that is delivered. The only reference of record in this application that mentions the viscosity of a liquid delivered by a pad is the '237 Patent, which describes viscosities of from 10,000 to 300,000 centipoise, which is in excess of the range called for by the claimed invention. Applicant has pointed this out, but the

Examiner has responded that "one cannot show nonobviousness by attacking references individually where the rejections are based on a combination of references." In this, the Examiner states a proposition that, while true, is irrelevant to this application. In the entire body of prior art of record there is only one disclosure of the viscosity of the liquid on the pad, and in that disclosure the viscosity is well outside the claimed range, e.g. "most preferably from about 50,000 to about 150,000 centipoise." See Column 13, lines 25-28. In pointing this out, the Applicant is not attacking the references individually. The Applicant is pointing out that the only viscosity disclosures in the entire body of art of record fails to disclose or suggest the viscosity claim limitation, and that the art of record suggest that one should use liquids that do not meet the viscosity limitation of the pending claims.

The Applicant did not commit the mistake of *In re Keller* and *In re Merck & Co.* In *In re Keller* and *In re Merck & Co.*, the applicants only addressed one reference and ignored the others, which is not the case here. Here, the Applicant's arguments are directed to the entire body of art of record.

At page 10 of the Office Action the Examiner argues that "the composition disclosed by the combined teachings of the references" has the same ingredients disclosed by the Applicant and for that reason would be expected to have the same viscosity as the Applicant's composition.² This is a fatally flawed argument, since ingredients can be combined in various ratios and proportions that give rise to various viscosities. If any proof of this is required, one need look no further than the '237 Patent, which the Examiner says discloses compositions with the same ingredients as are disclosed by the Applicants and that have viscosities well outside the claimed range. Since the '237 Patent is apparently one of the references combined by the

² The Examiner's reliance on "the combined teachings of the references" to support a rejection based on a single reference is puzzling. Clearly, the Examiner is relying on references other than the '624 Patent. Applicants' response to the Examiner's argument is based on the assumption that the Examiner has already made of record whatever teachings she is combining. Applicant respectfully requests that the Examiner clarify what teachings are being combined and, if necessary that all of the teachings that the Examiner is combining be made of record.

Examiner, the only fair conclusion that can be drawn by such a combination is that the resulting composition would *not* have the claimed viscosity.³

Since the art of record does not suggest the viscosity limitation of the claims (and indeed appears to teach away from it), what is the foundation of the Examiner's statement that the claimed viscosity "is expected"? If this expectation is founded on facts within the Examiner's personal knowledge, she is requested to provide a declaration setting forth those facts, as required by 37 CFR §1.104(d)(2). If this expectation is founded on art not of record, Applicant requests that it be made of record so that Applicant may respond to it.

As to the missing particle size limitation, the Examiner offers even less to support the assertion that this too would be "expected." The Examiner offers no discussion of the prior art, other than to concede that the prior art does not disclose this claim limitation. Indeed none of the prior art of record includes any disclosures concerning particle sizes. The Examiner advances a bare assertion that there would be a "reasonable expectation" that one of ordinary skill in the art would know to modify the '642 Patent by adopting the particle size limitations of the Applicant's claims. The Applicant cannot respond to a rejection that is not based on the disclosures of the art or other evidence. If the Examiner's "expectation" is founded on facts within the Examiner's personal knowledge, she is requested to provide a declaration setting forth those facts, as required by 37 CFR §1.104(d)(2). If this expectation is founded on art not of record, Applicant requests that the art be made of record so that Applicant may have a fair opportunity to respond to it.

The Examiner cites *In re Aller* with respect to the particle size claim element stating, "they do not impart patentability to the claims since it has been held that where the general conditions of a claim are disclosed in the art, discovering the optimum or workable ranges involves only routine skill in the art." *In re Aller*, 105 U.S.P.Q. 233 (CCPA 1955). *In re Aller* is not applicable to this situation because the "general conditions," namely particle size, are not

³ Applicant notes that the Examiner must consider the disclosures of the references as a whole when combining their teachings to support a rejection under 35 U.S.C. §103. MPEP §2141.02. If the Examiner wishes to combine references in the context of the viscosity of the compositions that they disclose, then the Examiner cannot ignore all of the viscosity data in those references.

disclosed in the '642 Patent. Indeed, the Examiner has admitted that the prior art does not teach this "general condition." Since the general conditions are not disclosed in the prior art one of ordinary skill in the art would not know how to routinely optimize the particle size to achieve the present invention. Even if the particle size was optimized, the Applicant's invention produces "a new and unexpected result which is different in kind and not merely in degree from the results of the prior art." *Id.* at 235. Therefore, *In re Aller* cannot be invoked because it only applies when the general conditions of a claim are disclosed in the prior art, while in this case and the '642 Patent is silent as to particle size.

Applicant believes that the basis for the Examiner's "expectations" concerning viscosity and particle size is the Applicant's own specification. The Applicant has discovered a way to overcome a deficiency in the prior art, resulting in an improved delivery device. The Examiner concedes at least twice that the prior art '642 Patent does not disclose the viscosity or particle size elements of the claimed invention. The Examiner simply asserts that it would have been obvious to have modified the prior art '642 Patent to practice the claimed invention. This assertion cannot be based on the content of the prior art, since the Examiner concedes that the prior art fails to disclose the Applicant's claim limitations, and the prior art affirmatively teaches away from some of those limitations. Only the Applicant's own disclosures provide the suggestions that the Examiner relies upon. It is fundamental that hindsight reconstruction of the claimed invention in light of an applicant's own disclosures is forbidden. *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992), (stating "[i]t is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious"); *In re Fine*, 837 F.3d 1071, 1075 (Fed. Cir. 1988), (stating "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention").

b) Rejection of Claim 19.

The Examiner has rejected claim 19 under 35 U.S.C. §103(a) as being unpatentable over U.S. 6,183,766 ('766 Patent) in view of the '642 Patent and further in view of U.S. 6,861,397 ('397 Patent) and U.S. 5,821,237 ('237 Patent).

Applicant respectfully traverses this rejection. To establish a *prima facie* case of obviousness the following must be shown: (1) the prior art references must teach or suggest all of the claimed elements; (2) there must be a reasonable expectation of success; and (3) there must be some suggestion or motivation to modify or combine the references. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991); MPEP §2143. The Examiner cites four references in an attempt to show that the present invention is obvious. However, the cited references when combined fail to meet the standard for establishing a *prima facie* case of obviousness.

The four references fail to teach or even suggest all of the claimed elements. As discussed above at pages 10-11, the references fail to teach the viscosity of the claimed composition and the only reference that discusses viscosity teaches away from the viscosities of the claimed invention. Therefore, the Applicant has addressed all of the art of record and has established that the prior art does not teach the claimed invention.

Again, the Examiner is using impermissible hindsight to find the present invention obvious over the four cited references. As discussed above, “[i]t is impermissible to use the claimed invention as an instruction manual or ‘template’ to piece together the teachings of the prior art so that the claimed invention is rendered obvious.” *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992). “One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.” *In re Fine*, 837 F.3d 1071, 1075 (Fed. Cir. 1988). None of the references cited by the Examiner teach or suggest anything about the viscosity of a composition. Further, the references do not teach or suggest how to measure the viscosity of the compositions disclosed and what measurement tools are used. Based upon the lack of teaching or suggestion, the Examiner has not shown how the cited references teach the claimed invention absent using the claimed invention as a “template” and piecing the teachings together. The Examiner needs to show, based upon the references, how the claimed invention is obvious when critical features of the invention are not taught or suggested.

The Examiner also asserts that many of the ingredients of the claimed invention are well known in the art and cites various references for teaching missing elements of the claim. The Examiner is piecing together the teachings of the cited references to come up with the claimed invention and the only way the Examiner can assert such a rejection is by using the claimed

invention as a road map impermissibly in hindsight to try to find the present invention. The references may disclose some of the ingredients that are included in the claimed invention, but none of them alone or when combined teach the claimed invention. One of ordinary skill in the art would not be able to take the four references and create the claimed invention without the knowledge of Applicant's invention. Therefore, the Examiner's rejection fails for use of impermissible hindsight. As such, the rejection should be removed.

Additionally, as discussed above, the art of record, especially the '237 Patent, teaches away from a low viscosity by teaching the use of thickeners to achieve a high viscosity. For example, the '237 Patent states that, "[p]referred emulsions have a high viscosity, of from about 10,000 to about 300,000 centipoise, more preferably from about 20,000 to about 200,000 centipoise, most preferably from about 50,000 to about 150,000 centipoise." Column 13, lines 25-28. In contrast to the high viscosities of the '237 Patent, the viscosities of the present invention are significantly lower and the specific values are necessary for the present invention to work. For example, at page 11, paragraph 46 of the Applicant's specification the viscosity values for the example compositions are illustrated. Example 1 showed a viscosity range of 2000-2800 cps; Example 2 showed a viscosity range of 2000-2400 cps; Example 3 showed a viscosity range of 2000-2500 cps; and Examples IV-VII showed viscosities ranging from 2200 to 6600 cps. Therefore, the '237 Patent teaches away from a composition having a low enough viscosity for the composition to substantially uniformly absorb onto the pad via capillary action and high enough to be substantially retained on the pad not the container.

Therefore, since the cited references do not teach or suggest each and every element, and there is no motivation or suggestion to combine the references, Applicant respectfully requests the rejection be removed.

CONCLUSION

In view of the foregoing remarks, Applicant respectfully requests consideration and allowance of the pending claims. Finally, Applicant respectfully submits a request for a personal interview with the Examiner, in order to further resolve any outstanding issues.

Authorization of Deposit Account

The Commissioner is hereby authorized to charge any fees which may be required during the entire pendency of this application, or credit any overpayment, to Deposit Account No. 18-0586. This authorization also hereby includes a request for any extensions of time of the appropriate length required upon the filing of any reply during the entire pendency of this application.

I hereby certify that this paper and the papers referred to herein as being transmitted, submitted, or enclosed herewith in connection with U.S. Serial No. 10/613,698 is/are being facsimile transmitted to the United States Patent and Trademark Office fax number 571-273-8300 on the date shown below.



Tamara Yonita

Date of Facsimile Transmission: June 5, 2006.

Respectfully submitted,
REED SMITH LLP



Tamara J. Yonita
Registration No. 53,813
William J. McNichol, Jr.
Registration No. 31,179
Maryellen Feehery
Registration No. 44,677
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103-7301
(215) 241-7988
Attorneys for Applicant